

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1066135	(X3) Date Survey Completed 11/02/2023
Name of Provider or Supplier Mansfield Dermatology	Street Address, City, State 130 Regency Parkway, Mansfield, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instruction manual, environmental logs, and confirmed in staff interview, the laboratory failed to monitor temperature and humidity requirements for the microscope, located in the laboratory director's office for 10 of 10 months in 2023. Findings included: 1. During a tour of the laboratory director's office on 11/03/2023 at 10:40 am, the surveyor observed the Olympus CX33 Biological Microscope (Serial #9E45461) on the desk. The microscope was used to perform slide reviews for dermatopathology diagnostic testing. 2. Review of Olympus CX33 Biological Microscope instruction manual revealed: "7. Specifications ... Operating environment ... Ambient temperature: 5 to 40C (41to 104F) Humidity: Max. 80% (31C or less) (without condensation)" 3. Review of the laboratory's environmental logs for 2023 revealed no documentation of temperature or humidity monitoring for the Olympus CX33 Biological Microscope. The laboratory was asked to provide documentation, and none was provided. 4. During the exit interview on 11</p>

/01/2023 at 12:10 pm, the Histotechnician was asked if temperature and humidity were monitored in the laboratory director's office, and she stated "No". This confirmed the above findings.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on direct observation, review of manufacturer's instruction manual, laboratory policy, maintenance log, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for ensuring 1 of 1 microscope was covered with a dust cover when not in use. Findings included: 1. During a tour of the laboratory director's office on 11/03/2023 at 10:40 am, the surveyor observed the Olympus CX33 Biological Microscope (Serial #9E45461) uncovered. The microscope was not in use the day of inspection. 2. Review of Olympus CX33 Biological Microscope instruction manual revealed: "Maintenance and storage ... 3. After using this product, store it in a dry place or cover it with a dust cover. If you need the dedicated dust over (made by Olympus), contact Olympus." 3. Review of the laboratory's policy titled "Microscope" revealed: "1. The microscope should be covered at the close of every day [sic]" 4. Review of the laboratory's microscope maintenance log revealed: "1. The microscope should be covered at the close of every day [sic]" 5. During the exit interview on 11/01/2023 at 12:10 pm, the Histotechnician confirmed the above findings.